REMARKS

Withdrawal of Species Election Requirement

Applicants are grateful for the express withdrawal of the species election requirement of July 7, 2005. 7/11/06 Office Action, page 2, second paragraph.

Claim Amendments

Claim 1 has been amended to delete “isotactic poly(methyl methacrylate)” and “syndiotactic poly(methyl methacrylate)”. Claim 1 has also been amended to move the glass transition temperature limitation from the preamble to the body of the claim. Claim 1 has been further amended to state that, “the shape memory polymeric material has a melting temperature, T_m”. Support for this amendment may be found, at least, on page 9, lines 20-29 of the specification as filed. Claim 1 has been further amended to state that “the shape memory polymeric material has rubber modulus and elasticity derived substantially from physical crosslinks formed by annealing the blend at a temperature greater than T_g and less than T_m”. Support for this amendment may be found in the preamble of claim 1 as filed and on page 13, line 1 of the specification as filed.

Article claims 11-14 have been rewritten to include the limitations of claim 1 expressly, rather than via incorporation by reference.

Claim 15 has been amended to make clear that polylactide copolymer is present as the crystalline polymer component of the shape memory polymeric material. Support for this amendment may be found in claim 1 as filed and the specification as filed at page 3, lines 24-26.

Claim Objections

Claims 11-14 stand objected to under 37 C.F.R § 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. 7/11/06 Office Action, page 2, third paragraph. Specifically, the Office Action states that “[e]ach of claims 11, 12, 13 and 14 is drawn to a particular product, yet each depends from a composition." *Id.*

Applicants respectfully submit that claims 11-14 do not violate 37 C.F.R. § 1.75. Strictly speaking, claims 11 to 14 are not dependent claims. They are independent claims written in shorthand form to incorporate by reference the limitations of claim 1. Thus, claims 11-14 do not depend from claim 1. Nevertheless, in order to expedite prosecution, Applicants have amended claims 11, 12, 13, and 14 to expressly include the limitations that were previously incorporated via reference to claim 1. Applicants therefore respectfully request the reconsideration and withdrawal of the objection to claims 11-14.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-5 and 11-16 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. 7/11/06 Office Action, page 2, penultimate paragraph. Specifically, the Office Action states,

> In claim 1 at line 8, the claim recites the inclusion of an "amorphous polymer selected from the group consisting of poly(vinyl acetate), poly(methyl acrylate), poly(ethyl acrylate, atactic poly(methyl methacrylate), ***isotactic*** *poly(methyl methacrylate) and* ***syndiotactic*** *poly(methyl(methyl methacrylate)* (emphases added)." Isotactic and syndiotactic polymers exhibit crystallinity which prevents them from being amorphous.

7/11/06 Office Action, paragraph bridging pages 2 and 3 (emphasis in original).

Claim 1 has been amended to delete "isotactic poly(methyl methacrylate)" and "syndiotactic poly(methyl methacrylate)" from the Markush group of amorphous polymers. Claims 11-14, which have been rewritten to include the limitations of claim 1, do not include "isotactic poly(methyl methacrylate)" and "syndiotactic poly(methyl methacrylate)" in the Markush group of amorphous polymers. Assuming that the rejection of claims 2-5,15 and 16 is based solely on their dependence from claim 1, Applicants respectfully request the reconsideration and withdrawal of the rejection of claims 1-5 and 11-16 under 35 U.S.C. § 112, second paragraph.

Provisional Nonstatutory Double Patenting Rejection over Application No. 10/958,435

Claims 1, 3, 11-14 and 16 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-127 of copending Application No. 10/958,435. 7/11/06 Office Action, page 3, penultimate paragraph.

Applicants thank the Examiner for pointing out the potential obviousness-type double patenting issue between the claims of the present application and those of co-pending application No. 10/958,435. As of 9/5/2006, the 10/958,435 application is awaiting its first office action. In view of the possibility that claims in the cited application or the present application will be amended before allowance, Applicants will defer responding to this provisional rejection until claims in the reference application are allowed, claims in the present application are otherwise allowable, and it is determined whether this provisional rejection becomes an actual rejection.

Provisional Nonstatutory Double Patenting Rejection over Application No. 10/683,314

Claims 1, 3, 11-14 and 16 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-105 of copending Application No. 10/683,314. 7/11/06 Office Action, page 4, first paragraph.

Applicants thank the Examiner for pointing out the potential obviousness-type double patenting issue between the claims of the present application and those of co-pending application No. 10/683,314. As of 9/5/2006, the 10/683,314 application is awaiting its first office action. In view of the possibility that claims in the cited application or the present application will be amended before allowance, Applicants will defer responding to this provisional rejection until claims in the reference application are allowed, claims in the present application are otherwise allowable, and it is determined whether this provisional rejection becomes an actual rejection.

Claim Rejections Under 35 U.S.C. § 102(b) or § 103(a) over Langer '084

Claims 1, 2, and 11-16 stand rejected under 35 U.S.C. § 102(b), as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,160,084 to Langer et al. ("Langer '084"). 7/11/06 Office Action, page 5, first paragraph. Applicants respectfully traverse the rejection to the extent it may be applicable to the claims as currently amended.

Langer '084 generally describes biodegradable shape memory polymer compositions, articles of manufacture thereof, and methods of preparation and use thereof. Langer '084 abstract. Langer's biodegradable shape memory polymer composition may be a biodegradable polymer blend. Langer '084, col. 10, ll. 18-22. Such blends can be prepared by blending the component polymers using a twin screw extruder. Langer '084, col. 10, l. 63 to col. 11, l. 2. Langer's shape memory polymer compositions may be shaped by heating them above the transition temperature of the polymer hard segments and then cooling them below the transition temperature of the polymer soft segments. Langer '084, col. 11, lines 9-13.

Applicants respectfully assert that claim 1 as currently amended is patentable over Langer '084 because Langer '084 does not teach Applicants' claim 1 annealing limitation. For an obviousness rejection to be proper, the Examiner must meet the burden of establishing a prima facie case of obviousness. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Establishing a prima facie case of obviousness requires that all limitations of the claim be taught or suggested by the prior art. *See, e.g.,* MPEP 2143.03; *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003); *In re Royka,* 490 F.2d 981, 985 (C.C.P.A. 1974). Applicants' claim 1, as currently amended, includes the limitation that "the shape memory polymeric material has rubber modulus and elasticity derived substantially from physical crosslinks formed by annealing the blend at a temperature greater than T_g and less than T_m". The practical significance of Applicants' claim 1 annealing step is illustrated by Figure 1 and the accompanying description in the last paragraph on page 9, both of the application as filed. Although melt blending produces a small amount of crystallinity in resulting blend (evidenced by the small endothermic flow at about 150°C in the upper curve in Figure 1), annealing the blend at a temperature greater than the glass transition temperature and less than the melting temperature produces much greater crystallinity (evidenced by the large endothermic flow at about 150°C in the lower curve in Figure 1). Because the elasticity associated with shape recovery is derived substantially from physical crosslinks, which themselves correspond to crystalline regions, the ability of the blend to function as a shape memory material is greatly enhanced by annealing.

Langer '084 does not teach or suggest Applicants' claim 1 annealing limitation. Langer '084 does not expressly describe annealing. And one of ordinary skill in the polymer arts knows that melt blending techniques used to form polymer blends, like Langer's twin screw extrusion (col. 10, l. 67), are typically conducted above the melting point of any crystalline polymer component. Also note that Langer's "methods of shaping the SMP compositions" would involve heating the composition above the melting point of any crystalline polymer component. Langer '084, col. 11, lines 9-13 ("The compositions can be formed into a first shape under appropriate conditions, for example, at a temperature above the T_{trans} of the hard segments, and allowed to cool below the T_{trans} of the soft segment(s)." (emphasis added)). Langer '084 thus does not teach or suggest Applicants' claim 1 limitation of "annealing the blend at a temperature greater than T_g and less than T_m". Accordingly, a prima facie case of obviousness based on Langer '084 has not been established against claim 1. A fortiori, claim 1 is not anticipated by Langer '084.

Given that claims 2 and 11-16 each include or further limit all the limitations of claim 1, they, too, are patentable over Langer '084. Applicants therefore respectfully request the reconsideration and withdrawal of the rejection of claims 1, 2, and 11-16 under 35 U.S.C. § 102(b) or 35 U.S.C. § 103(a) over Langer '084.

Claim Rejections Under 35 U.S.C. § 102(e) or § 103(a) over Langer '043

Claims 1, 2, and 11-16 stand rejected under 35 U.S.C. § 102(e), as anticipated by or, in the alternative, under 103(a) as obvious over U.S. Patent No. 6,388,043 to Langer et al. ("Langer '043"). 7/11/06 Office Action, page 6, first paragraph.

Langer '043 generally describes shape memory polymer compositions, articles of manufacture thereof, and methods of preparation and use thereof. Langer '043 abstract. Langer's shape memory polymer composition may be a polymer blend. Langer '043, col. 10, ll. 48-58. Such blends can be prepared by blending the component polymers using a twin screw extruder. Langer '043, col. 11, ll. 21-27. Langer's shape memory polymer compositions may be shaped by heating them above the transition temperature of the polymer hard segments and then cooling them below the transition temperature of the polymer soft segments. Langer '043, col. 12, lines 59-63.

Like Langer '084, Langer '043 does not teach or suggest Applicants' claim 1 limitation of "annealing the blend at a temperature greater than T_g and less than T_m". Langer '043 does not expressly describe annealing. And one of ordinary skill in the polymer arts knows that melt blending techniques used to form polymer blends, like Langer's twin screw extrusion (col. 11, ll. 21-27), are typically conducted above the melting point of any crystalline polymer component. Also note that Langer's "methods of shaping the SMP compositions" would involve heating the composition above the melting point of any crystalline polymer component. Langer '043, col. 12, lines 59-63. ("The compositions can be formed into a first shape under appropriate conditions, for example, at a temperature above the T_{trans} of the hard segments, and allowed to cool below the T_{trans} of the soft segment(s)." (emphasis added)). Langer '043 thus does not teach or suggest Applicants' claim 1 limitation of "annealing the blend at a temperature greater than T_g and less than T_m". Accordingly, a prima facie case of obviousness based on Langer '043 has not been established against claim 1. A fortiori, claim 1 is not anticipated by Langer '043.

Given that claims 2 and 11-16 each include or further limit all the limitations of claim 1, they, too, are patentable over Langer '043. Applicants therefore respectfully request the reconsideration and withdrawal of the rejection of claims 1, 2, and 11-16 under 35 U.S.C. § 102(b) or 35 U.S.C. § 103(a) over Langer '043.

Claim Rejections Under 35 U.S.C. § 102(e) or § 103(a) over Fujino

Claims 1 and 16 stand rejected under 35 U.S.C. § 102(e), as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 6,427,738 B1 to Fujino et al. ("Fujino"). (Although the 7/11/06 Office Action at page 6 describes Langer '043 as the basis for this rejection, the Examiner clarified in an August 17, 2006 phone conversation with Applicants' attorney that the rejection is based on Fujino.)

Fujino generally describes a vulcanized rubber comprising a rubber component containing natural rubber, in an amount of 20 to 70 parts by weight, and polybutadiene, in an amount of 30 to 80 parts by weight; a rubber matrix containing 5 to 55 parts by weight of carbon black and 5 to 55 parts by weight of silica per 100 parts per weight of the rubber component; a resin, and resin coated elongated cells having a length (L) to diameter (D) ratio (L/D) of at least 3. Fujino abstract. The vulcanized rubber can be used in the tread of tires to improve on-ice performance, wet properties and wear resistance in a well balanced manner. *Id.* The resin coated elongated cells may comprise an elongated resin. *See, e.g.,* Fujino, col. 2, lines 61-62. The elongated resin may be composed of both crystalline and amorphous polymers. Fujino, col. 7, lines 58-59. Specific crystalline polymers taught include, inter alia, polyethylene. Fujino, col. 7, line 67. Specific amorphous polymers taught include, inter alia, polymethylmethacrylate. Fujino, col. 8, l. 11. The rubber composition, including the elongated resin, may be prepared by "appropriate kneading, warming, and extrusion" using kneading apparatus such as "the Banburry [sic] mixer, the Intermix, [and] the Kneader". Fujino, col. 10, ll. 31-32. Under the conditions required to vulcanize the rubber, the elongated resin is melted. Fujino, col. 11, lines 45-55 ("Upon initiation of vulcanization, the viscosity of the rubber matrix contained in the rubber composition increases due to vulcanization before the rubber composition reaches its maximum vulcanization temperature. On the other hand, the viscosity of the phase of the elongated resin contained in the rubber composition decreases greatly due to melting.").

Like the Langer patents discussed above, Fujino does not teach or suggest Applicants' claim 1 limitation of "annealing the blend at a temperature greater than T_g and less than T_m". Fujino does not expressly describe annealing. And one of ordinary skill in the polymer arts knows that the melt kneading techniques described by Fujino for preparing the rubber composition (col. 10, ll. 18-23 and 30-34) are typically conducted at a temperature above the melting point of any crystalline resin component. It is also clear that the elongated resin phase is "melted" under the rubber vulcanization conditions. Fujino, col. 11, lines 45-55. Fujino thus does not teach or suggest annealing a crystalline/amorphous polymer blend at a temperature greater than the glass transition temperature of the blend and less than the melting temperature of the blend. Accordingly, a prima facie case of obviousness against claim 1 has not been established. A fortiori, claim 1 is not anticipated by Fujino.

Given that claim 16 depends directly from and further limits claim 1, Applicants respectfully request the reconsideration and withdrawal of the rejection of claims 1 and 16 under 35 U.S.C. § 102(e) or 35 U.S.C. § 103(a) over Fujino.

Claim Rejections Under 35 U.S.C. § 103(a) over (Langer '084 or Langer '043) + Nagai

Claims 1-5 and 11-16 stand rejected under 35 U.S.C. § 103(a), as being unpatentable over Langer '084 or Langer '043, either taken in view of U.S. Patent Application Publication No. US 2001/0004708 of Nagai ("Nagai"). 7/11/06 Office Action, page 7, third paragraph.

Nagai generally describes "intraocular ring of open ring shape when inserting, so that it can be inserted from a small incision, and after being inserted into the capsule, by engaging the engaging mechanisms having mutually complementary male and female structures provided at ends of the intraocular ring, the intraocular ring having a nearly same compressive load as in closed ring". Nagai abstract. Nagai repeatedly refers to the ring as being "made of an elastic material". Nagai abstract; page 1, paragraphs [0009],

[0011], and [0013]; claims 1, 3, and 5. Nagai paragraph [0056], which discusses materials suitable for forming the intraocular ring, is reproduced in its entirety below.

> [0056] Referring to FIG. 1(*a*) and FIG. 1(*b*), a ring **1** of this embodiment is composed of a biocompatible material such as poly (methyl methacrylate) (PMMA), polypropylene (PP), hydrogel, fibronectin, polysulfone, chondroitin sulfate, a compound of hyaluronic acid, or similar compound, a biopolymer such as hydroxyethyl methacrylate, N-vinyl pyrrolidone, vinyl alcohol, or collagen, an elastomer such as silicone rubber, acrylic rubber, or their mixture or copolymer, a material such as polyethylene, vinyl chloride, poly (vinylidene fluoride), polyurethane, ethylene-vinyl acetate copolymer, siloxanyl styrene, similar material, and also a polymer such as polyurea, polyether, polyester, or copolysiloxane, a polymer such as polyacrylate or polymethacrylate, methyl methacrylate, styrene, methyl styrene, vinyl pyridine, similar copolymer, a copolymer such as N-alkyl, N,N-dialkyl acrylamide, or methacrylamide, or other shape memory material.

Nagai, pages 2-3, paragraph [0056].

Applicants respectfully assert that their claims are patentable over Langer ‘084 or Langer ‘043 in view of Nagai for at least three reasons. First, the cited references collectively fail to teach or suggest Applicants’ claim 1 annealing limitation. Second, claims 3 and 4 are further patentable because Nagai would not motivate a skilled artisan to use poly(vinylidene fluoride) in the shape memory compositions of Langer ‘084 and Langer ‘043. Third, claim 5 is further patentable because none of the cited references teaches the use of poly(vinylidene chloride).

1. The Cited References Fail to Teach Applicants’ Claim 1 Annealing Limitation

As noted above, Langer ‘084 and Langer ‘043 fail to teach or suggest Applicants’ claim 1 limitation of “annealing the blend at a temperature greater than T_g and less than T_m”. Nagai does not remedy this failure. As far as Applicants can tell from the poor Japanese-to-English translation that is Nagai, the reference does not describe any techniques for processing the paragraph [0056] polymers or forming the ring from them. Langer ‘084, Langer ‘043, and Nagai therefore fail to teach or suggest Applicants’ claim 1 annealing limitation.

2. Nagai Would Not Motivate a Skilled Artisan to Substitute PVDF into the Langer Compositions

Applicants' claims 3 and 4 require the use of poly(vinylidene fluoride). Applicants respectfully disagree with any assertion that one skilled in the art would be motivated by Nagai to use poly(vinylidene fluoride) ("PVDF") in the compositions of Langer '084 or Langer '043. The Examiner has asserted that "[t]he reference to Nagai shows at paragraph [0056] that poly vinylidene fluoride polymer is often employed as a shape memory polymer". 7/11/06 Office Action, page 7, penultimate paragraph. "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." MPEP 2141.02(IV) (emphasis in original). Although Nagai paragraph [0056] uses the term "shape memory material", there is nothing about Nagai's intraocular ring that requires a shape memory material. Nagai repeatedly uses the term "elastic material" to describe the composition used to form the intraoculur ring. Nagai abstract; page 1, paragraphs [0009], [0011], and [0013]; claims 1, 3, and 5. It would be clear to one skilled in the art that elasticity is required for Nagai's ring, but that true shape memory behavior is not. (For a reminder of what defines a shape memory polymer, see the paragraph bridging pages 1 and 2 of Applicants' specification.) If Nagai's ring required shape memory behavior, there would be some discussion of how to form the permanent and temporary shapes of the ring, and how to trigger the reversion from the temporary to the permanent shape. There is none.

More importantly and contrary to the alleged teaching of Nagai, poly(vinylidene fluoride) is not, by itself, a shape memory polymer. According to MATWEB, it has a glass transition temperature of -42 to -25°C and a melting temperature of 135 to 175°C. *See* copy of http://www.matweb.com/search/SpecificMaterialPrint.asp?bassnum=O1950, visited August 4, 2006, submitted with co-filed Information Disclosure Statement. Poly(vinylidene fluoride) is therefore rigid between its glass transition temperature of -42 to -25°C and its melting point of 135 to 175°C. It has no capacity for maintaining a temporary shape above room temperature or reverting from a temporary shape to a permanent shape by heating to a temperature greater than room temperature. In short, poly(vinylidene fluoride) is not a shape memory polymer, and Nagai's erroneous suggestion to the contrary would not be enough to fool one skilled in the polymer arts. Nagai therefore would not motivate one skilled in the polymer arts to substitute poly(vinylidene fluoride) for one of the crystalline polymers recited in Langer '084 and Langer '043. Claim 3, which requires poly(vinylidene fluoride), is therefore further patentable over the cited references.

3. The Cited References Do Not Teach Poly(vinylidene chloride)

Applicants' claim 5 requires the use of poly(vinylidene chloride). Langer '084, Langer '043, and Nagai collectively fail to teach or suggest the use of poly(vinylidene chloride). Claim 5 is therefore further patentable over the cited references.

4. Summary

For all of the above reasons, the collective teachings of Langer '084, Langer '043, and Nagai do not support a prima facie case of obviousness against Applicants' claim 1. Given that claims 2-5 and 11-16 each include or further limit all the limitations of claim 1, and given that claims 3-5 are further patentable over the cited references for the reasons discussed above, Applicants respectfully request the reconsideration and withdrawal of the rejection of claims 1-5 and 11-16 under 35 U.S.C. § 103(a) over Langer '084 or Langer '043 in view of Nagai.

New Claim

Claim 19 has been added to further claim the invention. Support for claim 19 may be found on page 9, lines 22-23 of the specification as filed.

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance is requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130 maintained by Applicants' Attorneys.

Respectfully submitted,

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